



# Development and proof of principle of new clinical applications of theranostics solutions

---

**Update 04-07-2023: Slides 20 & 21 added for clarification**

---

IHI call 5 – topic 2

**Oussama KARROUM, PhD**  
IHI Scientific Project Officer  
27.06.2023

# Before we start...

- All information regarding future IHI call topics is indicative and subject to change. Final information about future IHI calls will be communicated after approval by the IHI Governing Board.
- We are recording this session and it will be published on the IHI website and B2Match platform.
- We will also publish the presentation slides.

# Before we start...

## Questions

- Please use the **'Join the discussion' function** at the bottom right of the screen to ask questions.

# Today's webinar

**Will not cover** rules & procedures or financial parts

- These webinars are on the IHI website

## Will cover:

- Introduction to IHI programme
- IHI Call Topic:
  - Challenge, need for public-private collaborative research
  - Scope, outcomes & impacts, budget
- Proposal preparation tips & participant pitches

# Innovative Health Initiative

Public private partnership between:

- the **European Union** represented by the European Commission
- &
- **Healthcare industry associations:**
  - **COCIR** (medical imaging, radiotherapy, health ICT and electromedical industries)
  - **EFPIA**, including **Vaccines Europe** (pharmaceutical and vaccine industries)
  - **EuropaBio** (biotechnology industry)
  - **MedTech Europe** (medical technology industry)

# IHI's General objectives

Through **cross sectoral, pre-competitive** collaboration:

- Turn health research and innovation into **real benefits for patients and society**
- Deliver safe, effective health innovations that **cover the entire spectrum of care** – from prevention to diagnosis and treatment – particularly in **areas where there is an unmet public health need**
- Make Europe's health industries **globally competitive**.

# IHI Funding model

As a **public private partnership**, IHI's projects are funded by:

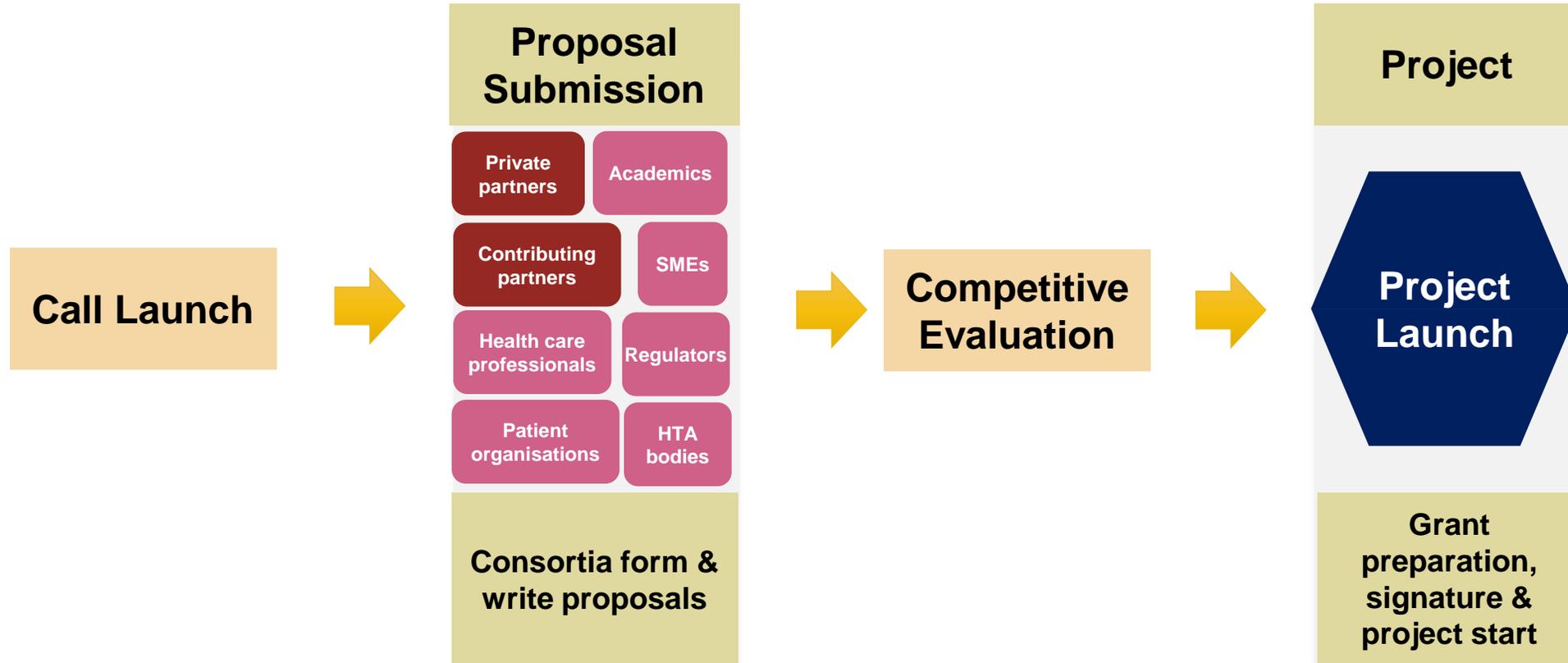
- **EU cash contributions**

- Primarily supporting universities, research organisations, patient organisations, small and medium-sized enterprises (SMEs), and mid-sized companies.\*

- **IHI industry associations and contributing partners**

- Must **provide at least 45% of total project eligible costs** (usually via researchers participating in the project)

# How IHI works: Single-stage procedure





Development and proof of principle  
of new clinical applications of  
theranostics solutions

# The challenge

- Multi-modal theranostics solutions, currently dominated by radionuclide-based therapy and companion diagnostics are emerging as safe, personalised, and effective approaches for the treatment of several diseases.
- However, use of such therapies is limited:
  - to a few specialised centres with the need to increase clinical treatment capacities,
  - in terms of the arsenal of theranostics

# Need for public-private, cross-sector collaboration

- Theranostic solutions require a highly multidisciplinary team of specialists for their clinical application and integration in a patient treatment workflow.
- Therefore, a cross-sectorial collaboration is necessary for clinical deployment of theranostic solutions between
  - Academia
  - Healthcare professionals
  - Health industry sectors

# Scope of the topic

Applicants should identify a **disease(s) of unmet public health need** and **explain their choice with relevant evidence where possible.**

**All the following objectives should be addressed:**

- Develop innovative **multi-modal theranostic solutions** including radiopharmaceuticals and/or non- radioactive theranostic solutions. Consider conducting proof of concept clinical trials.
- Develop **tools for the quantification of the chosen disease(s)** through development of novel modalities for planning and monitoring of patients care.
- Facilitate the **development of tools to increase European theranostic manufacturing capabilities and treatment capacities**, including guidance on quality assurance and improving logistics of supply at the EU level.
- Develop **education & training materials on the deployment of multi-modal theranostic** solutions and their integration in clinical settings
- Consider the **potential regulatory impact** of the results and as relevant develop a strategy/plan for generating appropriate evidence as well as engage with regulators

# Expected outcomes

- **Patients** will benefit from increased treatment efficacy, reduction of time to treat, fewer side effects, and reduced duration of hospitalisation.
- **Healthcare professionals** benefit from education, training on theranostic treatment approaches, recommendations, and clinical guidelines on the most appropriate use of theranostic solutions.
- **European healthcare systems** benefit from a broader spectrum of theranostic treatments and improved cost-effectiveness and affordability of theranostic solution.
- **Technology developers, healthcare professionals and patients** benefit from increased information on the sensitivity, quantification, stratification and staging of diseases.

# Expected impacts

- **Improved availability of effective treatments** for patients based on multi-modal theranostic solutions.
- **Stronger resilience and improved strategic autonomy** of Europe's health systems, for example, by implementing new manufacturing capabilities for medical radioisotopes and radiopharmaceuticals.
- Depending on the disease area of the application, **contributing to the objectives** of Europe's Beating Cancer Plan and to the Horizon Europe Mission on Cancer.

# Dissemination, exploitation & communication

- **Reserve budget** for effective Dissemination, exploitation & communication
- **Describe the dissemination, exploitation and communication measures** that are planned, and the target group(s) addressed, in particular:
  - Encourage the uptake of the results of the project through a strong communication and outreach plan
  - Allocating appropriate resources to explore synergies with other relevant initiatives and projects
  - If applicable, elements in line with the Availability, Accessibility and Affordability (3A) provisions

# Budget

Total available IHI financial contribution for this topic: 25 Million EUR

IHI financial **contribution** estimated for one proposal to address the outcomes: **10 to 12 Million EUR**

Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

# Budget

Total available IHI financial contribution for this topic: 25 Million EUR

IHI financial **contribution** estimated for one proposal to address the outcomes: **10 to 12 Million EUR**

Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

IHI financial  
contribution:  
12 Million EUR



# Budget

Total available IHI financial contribution for this topic: 25 Million EUR

IHI financial **contribution** estimated for one proposal to address the outcomes: **10 to 12 Million EUR**  
Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

IHI financial  
contribution:  
12 Million EUR



Industry & CPs  
Contribution:  
12 Million EUR\*

# Budget

Total available IHI financial contribution for this topic: 25 Million EUR

IHI financial **contribution** estimated for one proposal to address the outcomes: **10 to 12 Million EUR**  
Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

IHI financial  
contribution:  
12 Million EUR



Industry & CPs  
Contribution:  
12 Million EUR\*

Project Budget  
24 Million EUR

# Simplified budget example

## Single-stage call proposals

Type of participant	Total eligible costs + ICAA	Funding rate	Reimbursed eligible costs	Contributions (IKOP,FC,ICAA)
<b>'Public partners'</b> (Universities, hospitals, SMEs, patient orgs, regulators..)	15 million	100%	15 million	0
<b>Private members &amp; contributing partners</b> (requested funding = 0)	15 million	100%	0	15 million
<b>Private members &amp; contributing partners</b> ( <u>'Hybrid'</u> )	10 million	100%	5 million	5 million
<b>Total</b>	<b>40 million</b>	<b>100%</b>	<b>20 million (50%)</b> Public funds	<b>20 million (50%)</b> Private funds

# Simplified budget example

## Two-stage call Full proposal

Not eligible for funding: pre-identified private members and contributing partners  
Large companies with annual turnover > 500 M

Type of participant	Total eligible costs + IKAA	Funding rate	Reimbursed eligible costs	Contributions (IKOP,FC,IKAA)
<b>'Public partners'</b> (Universities, hospitals, SMEs, patient orgs, regulators..)	20 million	100%	20 million	0
<b>Pre-identified Private members and Contributing partners</b> (not eligible for funding)	20 million	100%	0	20 million
<b>Total</b>	<b>40 million</b>	<b>100%</b>	<b>20 million (50%)</b> Public funds	<b>20 million (50%)</b> Private funds



# Proposal Submission & Evaluation



# Proposal Template: Parts A, B & Annexes

- **Part A** is administrative & researcher data that is entered in webforms.
- **Part B** is the **narrative part** that includes three sections:
  - Excellence
  - Impact
  - Quality and efficiency of the implementation
- **Read instructions** in proposal template **very carefully**
- **Annexes:**
  - Participant type
  - Budget details
  - Coordinator declaration
  - If relevant, IKAA
  - Clinical studies template\*

\*If no clinical studies included in the proposal, please upload a statement to confirm that no clinical studies is foreseen.

# Evaluation Criteria (1/2)

## ● Excellence

- Clarity and pertinence of the project's objectives, and the extent to which the proposed work is ambitious, and goes beyond the state of the art.
- Soundness of the proposed methodology, including the underlying concepts, models, assumptions, interdisciplinary approaches, appropriate consideration of the gender dimension in research and innovation content, and the quality of open science practices, including sharing and management of research outputs and engagement of citizens, civil society and end users where appropriate.

## ● Impact

- Credibility of the pathways to achieve the expected outcomes and impacts specified in the work programme, and the likely scale and significance of the contributions due to the project.
- Suitability and quality of the measures to maximise expected outcomes and impacts, as set out in the dissemination and exploitation plan, including communication activities.

# Evaluation Criteria (2/2)

- **Quality and efficiency of the implementation**
  - Quality and effectiveness of the work plan, assessment of risks, and appropriateness of the effort assigned to work packages, and the resources overall
  - Capacity and role of each participant, and extent to which the consortium as a whole brings together the necessary expertise.



- Tips for applicants

# Tips for applicants

- **Read all the call-relevant material, especially the topic text**  
<https://www.ihl.europa.eu/apply-funding/future-opportunities>
- **Watch the “Rules and Procedures” and “preparing the financial part of the proposal” webinars**

# Tips for applicants

- Form your consortium **early**
  - Always think “**public-private partnership**”
  - Include partners bringing **in-kind contributions**
- Ensure that **all information requested in the call text and proposal template** is provided to allow the evaluation experts to easily assess your proposal against the evaluation criteria
- Consider & plan for the potential **regulatory impact** of results

# Key points

## Proposals

- **Read the call text** very carefully
- Follow all the guidance in the **proposal template**
- Reserve dedicated **funding for communication & sustainability**

## Finding consortium partners

- Be proactive
- **Start working now!**

# Finding project partners

You'll need to build or join a consortium!

- Network with **your contacts & IHI Call days participants:**
- <https://ihi-call-days.ihi.b2match.io/>
- Use EU Funding & Tenders portal **partner search tool:**
  - <https://europa.eu/!QU87Nx>
- Get in touch with your **IHI national contact point:**
  - <https://europa.eu/!D7jyMy>
- Network on social media:
  - [www.twitter.com/IHIEurope](http://www.twitter.com/IHIEurope)
  - [be.linkedin.com/company/innovative-health-initiative](https://be.linkedin.com/company/innovative-health-initiative)

# Pitching Session

Today 27 June 2023, 15:10 – 16:10 CEST

Join via the B2Match platform: <https://ihi-call-days.ihi.b2match.io/>

Number	First Name	Last Name	Job position	Organization	Title of the presentation
1	Ralf	Hoffmann	Principal Scientist	Philips	Prostate Cancer Theranostics
2	Ana	Blanco Sanchez	Grants and Innovation Coordinator	Quibim SL	Transforming imaging data into actionable predictions
3	Efrain	Araujo Perini	R&D Project Manager	Ion Beam Applications	Broadening EU cancer patients access to new theranostics solutions: Proof of concept on securing EU onshore industrial and reliable supply of 211Astatine
4	Sampath	Kandala	Oncology Solutions General Manager	GE Healthcare	Enabling broader access to Theranostics solution in Europe
5	Aureli	Soria-Frisch	Director of Neuroscience BU	Starlab Barcelona	Neurotechnology as a Service (NTXaaS)

# How to book your meetings via the B2Match platform

Book your meetings in **4** easy steps

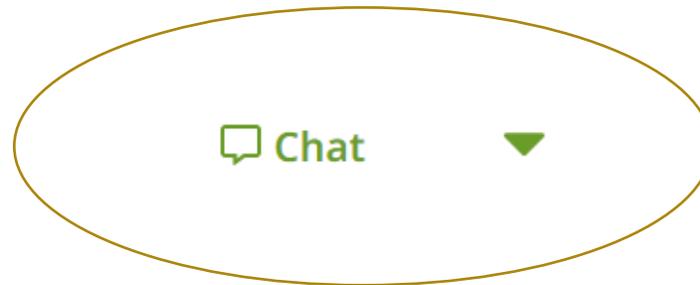
1. Make yourself available
2. Look for partner on the participants or organisation tab
3. Select date, time, attendees (up to eight per meeting), add message
4. Send the meeting request and wait for the reply

Step by Step guide on how to book meetings: <https://europa.eu/!FkjV9n>



# Questions time

If you want to ask a question please use the chat function on the right corner of your screen



# #IHICallDays

## Call 5



26 June

15:00-16:30 IHI rules & procedures

27 June

10:00-12:10 Non-animal approaches for health technologies

27 June

14:00-16:10 Theranostics solutions

28 June

14:00-16:10 Stroke management

29 June

10:00-12:10 Synthetic data generation

29 June

14:00-15:30 The financial part of the proposal

**Online event**

**Register now**



# Marketplace

## Marketplace

1

291 Opportunities found

Search

2  PROJECT COOPERATION (291)

4

### PROJECT COOPERATION

Updated on June 21, 2023

#### EEG based Triage of Stroke Patients

What type of organisation are you looking for? (Question for consortium/coordinator seeking partners)

What kind of expertise are you looking for? (Question for consortium/coordinator seeking partners)

### PROJECT COOPERATION

Updated on June 21, 2023

#### Medical image analysis and segmentation

We would like to join a consortium and can contribute the following expertise:

Medical image data are used in a variety of ways for diagnosis, treatment planning, monitoring of interventions, observation of condition changes and documentation. Common image modalities range from

### PROJECT COOPERATION

Updated on June 21, 2023

#### Remote vital functions monitoring, evaluation and smart interventions

Our research center focuses on the collection, remote monitoring, and evaluation of vital data.

What do we bring to the consortium?

3

### CALL TOPICS



Call 5 | Improved prediction, detection, and treatment approaches for comprehensive stroke management (36)



Thank you for your attention

[ihi.europa.eu](http://ihi.europa.eu)



We are taking now a 5  
minutes break



# Pitching Session

Today 27 June 2023, From 15:00 **Brussels time**

Join via the **B2Match platform**: <https://ihi-call-days.ihi.b2match.io/>

Number	First Name	Last Name	Job position	Organization	Title of the presentation
1	Ralf	Hoffmann	Principal Scientist	Philips	Prostate Cancer Theranostics
2	Ana	Blanco Sanchez	Grants and Innovation Coordinator	Quibim SL	Transforming imaging data into actionable predictions
3	Efrain	Araujo Perini	R&D Project Manager	Ion Beam Applications	Broadening EU cancer patients access to new theranostics solutions: Proof of concept on securing EU onshore industrial and reliable supply of 211Astatine
4	Sampath	Kandala	Oncology Solutions General Manager	GE Healthcare	Enabling broader access to Theranostics solution in Europe
5	Aureli	Soria-Frisch	Director of Neuroscience BU	Starlab Barcelona	Neurotechnology as a Service (NTXaaS)

# ProCaT

Prostate Cancer Theranostics

Ralf Hoffmann

Philips Research

ralf.hoffmann@philips.com

Topic number (2)

# ProCaT

## Challenges

- High-Risk, localized/locally advanced (LP/LAP) prostate cancer is challenging to treat as the risk of disease relapse is 50-60% within 5 years after primary, local treatment (e.g., surgery);
- 3-6 months neo-adjuvant androgen deprivation therapy (NADT) may improve the post-surgical progression-free survival if the endpoint of MRD (min residual disease) on pathology is met;
- Only 30-40% of patients treated with this regime will reach the MRD endpoint. To improve risk assessment:
  - selection of the responding patients is key;
  - Treatment alternatives for the non-responding patients need to be developed;

## Objectives

- Provide a **theranostics solution** to improve outcomes for patients with high-risk LC/LAP;
- Provide **prospective clinical evidence** that an IVD based on the diagnostic biomarker selects **NADT responders** with high accuracy;
- Provide pre-clinical (or potentially initial clinical) evidence that targeting the biomarker related target may serve as a new treatment option for the **NADT non-responders**;

# ProCaT

## Technical goals

- Implement an IVD for the selection of NADT responders and prospectively test the IVD in a **proof-of-concept clinical trial**;
- Perform **pre-clinical (or initial clinical) proof of concept studies** (*in vitro* & *in vivo*) to demonstrate the potential of a novel nano-technology based therapeutics based on the IVD biomarker to treat NADT non-responders;

# ProCaT

## Economical impact

- Molecular IVD product for high-risk LP/LAP patient selection to NADT;
- Patents and publications on the development of a novel diagnostics/therapeutics;

## Expected duration / budget

- Duration: 60 months; budget in k€: t.b.d.



# ProCaT

## Partners

- Philips
- Karolinska University Hospital/Karolinska Institutet (tbd)
- Clinical partner(s)
  - Pharma
  - IVD
- Biotech (SME)
  - Academic
- Regulatory (IVD; Pharma)

# Pitching Session

Today 27 June 2023, From 15:00 **Brussels time**

Join via the **B2Match platform**: <https://ihi-call-days.ihi.b2match.io/>

Number	First Name	Last Name	Job position	Organization	Title of the presentation
1	Ralf	Hoffmann	Principal Scientist	Philips	Prostate Cancer Theranostics
2	Ana	Blanco Sanchez	Grants and Innovation Coordinator	Quibim SL	Transforming imaging data into actionable predictions
3	Efrain	Araujo Perini	R&D Project Manager	Ion Beam Applications	Broadening EU cancer patients access to new theranostics solutions: Proof of concept on securing EU onshore industrial and reliable supply of 211Astatine
4	Sampath	Kandala	Oncology Solutions General Manager	GE Healthcare	Enabling broader access to Theranostics solution in Europe
5	Aureli	Soria-Frisch	Director of Neuroscience BU	Starlab Barcelona	Neurotechnology as a Service (NTXaaS)

# IHI Call Days | Call 5



**Topic 2: Development and proof of principle of new clinical applications of theranostics solutions**



**Quibim**

**Transforming imaging data into actionable predictions**

Contact person name: Ana Blanco

Organisation: Quibim SL

E-mail: [anablanco@quibim.com](mailto:anablanco@quibim.com)

Link to:

<https://ihi-call-days.ihi.b2match.io/participations/191964>

# Challenges and objectives

## From imaging data to Precision Medicine

Every day 10 million imaging exams are performed globally.

These are 10 million life and death diagnoses that doctors must make.

But what if we could go much further than the eye can see?

What if AI-powered imaging could not only assist doctors in diagnosis now, but predict the future evolution of patient health?

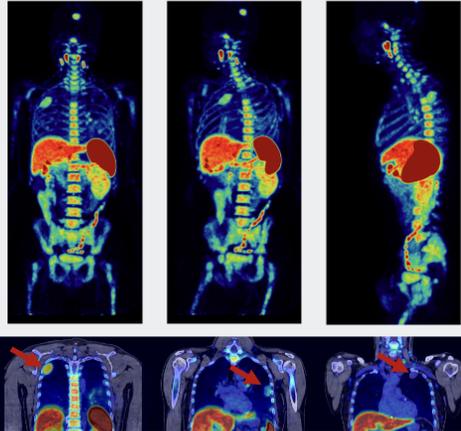
At Quibim, we design pioneering tools that unlock the data hidden in medical images to not only understand each patient, but also predict their outcomes.



# Main activities

Case study | Theranostics

## Characterization and quantification of radiotracer efficacy in PET/CT



- Target PET/CTs
- Melanoma, RCC, NSCLC, CLC, HNSCC, etc.

### → Challenge

Can Quibim stratify and assess subjects, organs and/or lesions predicting radiological response and assessing the MoA of the treatment, using the imaging biomarkers extracted in the baseline scan (pre-treatment) and/or 1st on-treatment scan (early post-treatment)?

### → Solution

The methodology developed by Quibim allows the achievement of the following milestones:

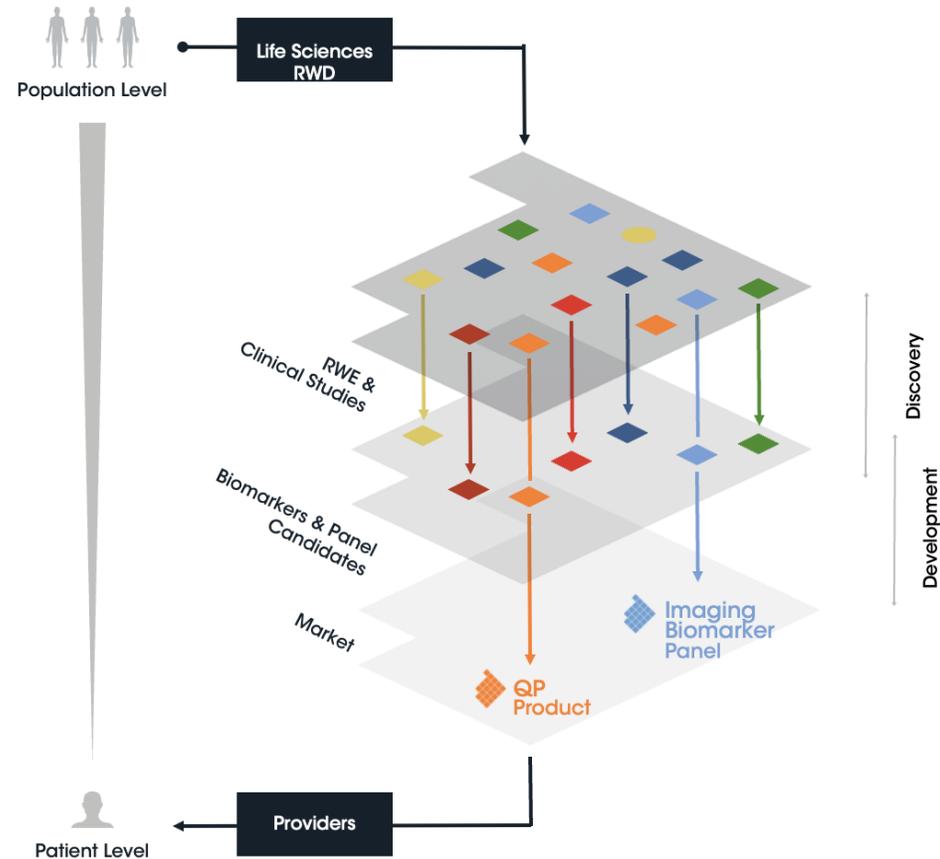
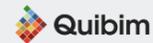
- M-1 To segment the entire lesion volume by differentiating between the central zone and the peritumoral ring.
- M-2 To extract imaging biomarkers from the segmented lesions.
- M-3 To predict the radiological response of the lesions from the biomarkers extracted in the baseline scan (pre-treatment), or in the 1st on-treatment scan (early post treatment, 4-6 weeks) or in the combination of both scans (change from baseline to on-treatment).
- M-4 To explore the actionable predictions of the imaging biomarkers to assess (M-4.1) the presence of immune related adverse events (irAEs), (M-4.2) to differentiate progressors from pseudo-progressors and (M-4.3) the mechanisms of action of the treatment.
- M-5 To assess coincident lesions among timepoints as well as the total lesion load through the generation of parametric maps.
- M-6 To differentiate healthy from tumor tissue.

# Expertise and resources offered

## With a unique model of partnership...

Working with physicians and biopharma partners to identify:

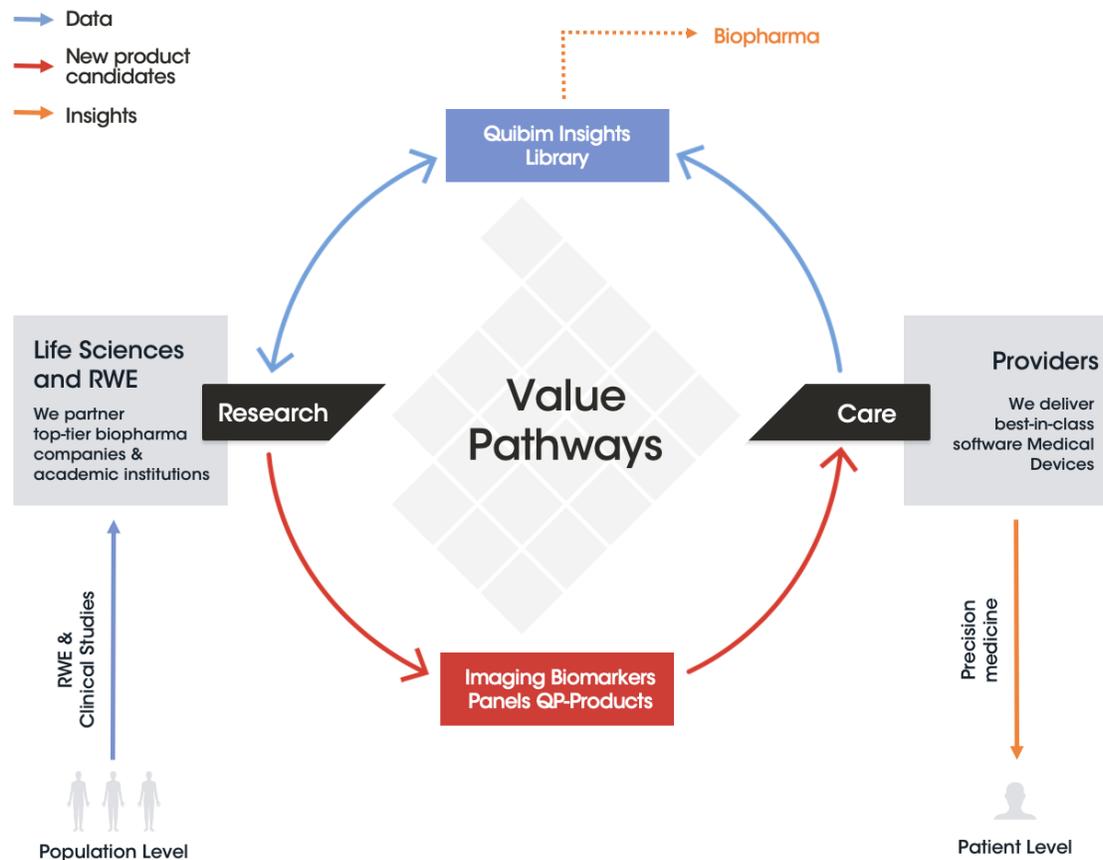
- Panels: New imaging biomarkers for outcomes prediction
- Products: New tools for data management and analysis, marketed as a medical device



# Expertise requested

...that connects research with personalized care

Physicians, researchers and biopharma partners work with Quibim to extract the latest insights in cancer and other diseases using medical imaging



# Pitching Session

Today 27 June 2023, From 15:00 **Brussels time**

Join via the **B2Match platform**: <https://ihi-call-days.ihi.b2match.io/>

Number	First Name	Last Name	Job position	Organization	Title of the presentation
1	Ralf	Hoffmann	Principal Scientist	Philips	Prostate Cancer Theranostics
2	Ana	Blanco Sanchez	Grants and Innovation Coordinator	Quibim SL	Transforming imaging data into actionable predictions
3	Efrain	Araujo Perini	R&D Project Manager	Ion Beam Applications	Broadening EU cancer patients access to new theranostics solutions: Proof of concept on securing EU onshore industrial and reliable supply of 211Astatine
4	Sampath	Kandala	Oncology Solutions General Manager	GE Healthcare	Enabling broader access to Theranostics solution in Europe
5	Aureli	Soria-Frisch	Director of Neuroscience BU	Starlab Barcelona	Neurotechnology as a Service (NTXaaS)

# IHI Call Days | Call 5

Topic 2 - Development and proof of principle of new clinical application of multi-modal theranostic solutions

- **Broadening EU cancer patients access to new theranostics solutions:  
Proof of concept on securing EU onshore industrial and reliable supply of <sup>211</sup>Astatine**

T <sup>211</sup>A T i 4 EU

Efrain Perini  
Ion Beam Applications (IBA)  
[Efrain.Perini@iba-group.com](mailto:Efrain.Perini@iba-group.com)



Links to:

- [Marketplace opportunity](#)
- [Participant profile](#)



# What do we want to achieve?

## SAMIRA action plan

#EUSamira #EUCancerPlan  
#WorldCancerDay



Secure the domestic supply life-saving radioisotopes in the European Union

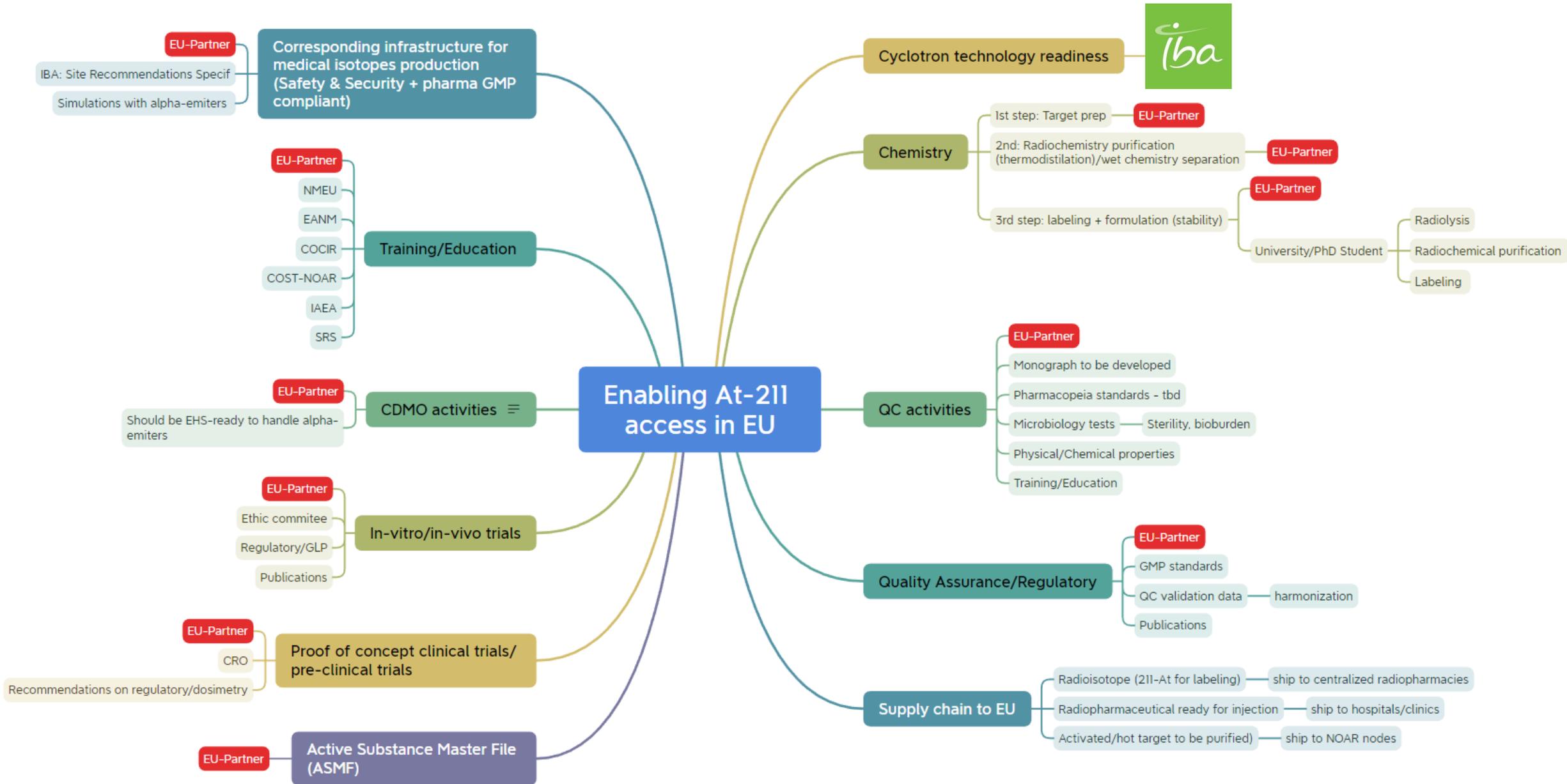


Long-term sustainability and resilience of onshore radioisotope supply



Enhance safety and security (dosimetry, waste from medical applications, etc)

# Technical challenges & main activities:



# Expected results & Impacts

T<sup>211</sup>A T i 4 EU

In 4 years, we (the consortium) will provide EU with **technology readiness** to **produce <sup>211</sup>At** radioisotope & radiopharmaceuticals (**clinical grade**) enabling onshore industrial scale up of a reliable supply chain capable to secure and attend the unmet demand for **<sup>211</sup>At TAT new drugs** proof of concept clinical trials, and speed up market authorizations to broaden EU cancer patient's access to theranostics.

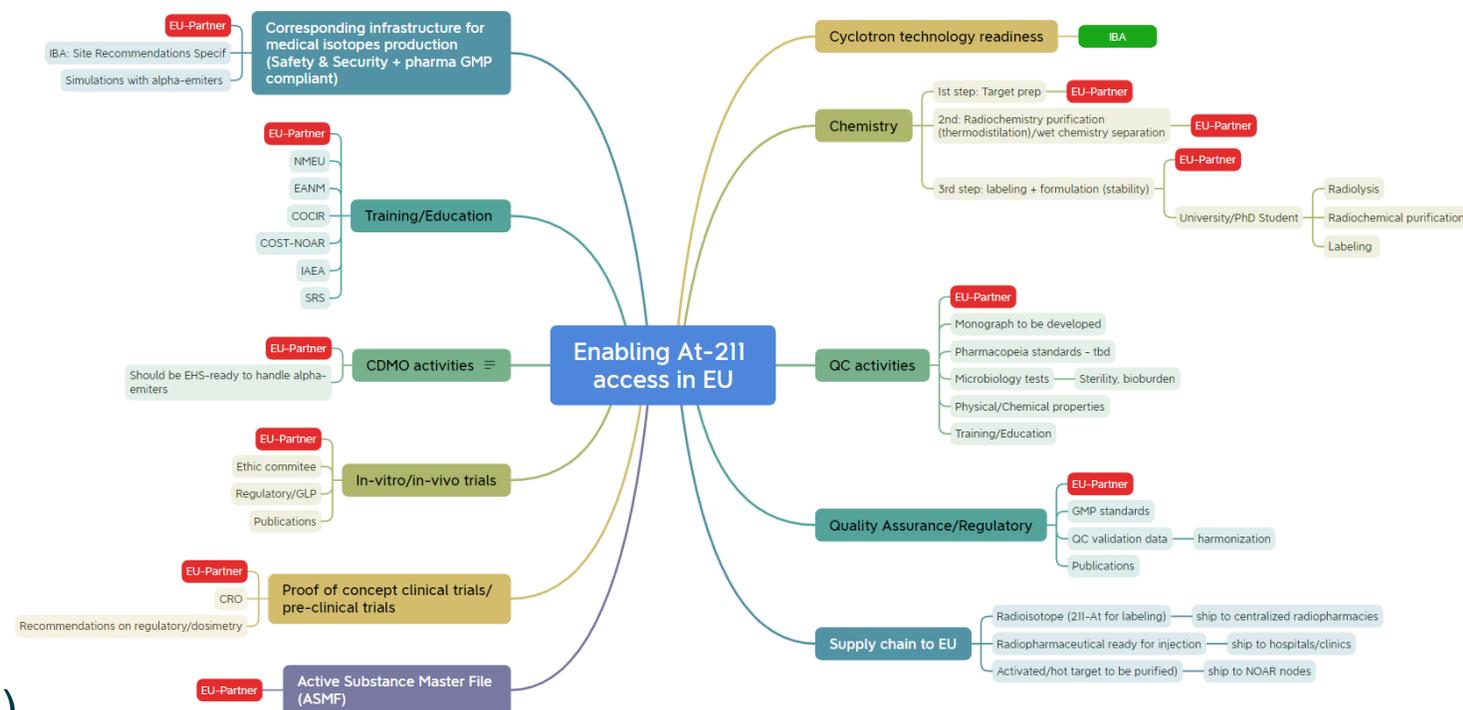


# Expertise and resources offered

- IBA will bring cutting-edge technology readiness for Alpha-Isotopes production (cyclotron-based), optimized to At.
  - Worldwide tech-industry key player with 37+ years of experience and 350+ cyclotrons installed on 5 continents
- **6,5M€ in-kind contributions**

# Expertise requested

- Chemistry/Radiochemistry:
  - Purification, labeling and formulation
- Pharma companies
- Health Care companies
- CDMO/CRO
- Academia & Research Institutes
- Industry & Associations
- Patients & Medical Associations
- SMEs, start-ups, tech companies
- Regulatory Support (Scientific Advice - EMA)



Questions?  
Thank you!

Efrain Perini  
Ion Beam Applications (IBA)  
[Efrain.Perini@iba-group.com](mailto:Efrain.Perini@iba-group.com)



# Pitching Session

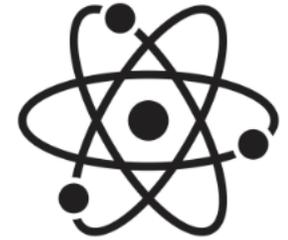
Today 27 June 2023, From 15:00 **Brussels time**

Join via the **B2Match platform**: <https://ihi-call-days.ihi.b2match.io/>

Number	First Name	Last Name	Job position	Organization	Title of the presentation
1	Ralf	Hoffmann	Principal Scientist	Philips	Prostate Cancer Theranostics
2	Ana	Blanco Sanchez	Grants and Innovation Coordinator	Quibim SL	Transforming imaging data into actionable predictions
3	Efrain	Araujo Perini	R&D Project Manager	Ion Beam Applications	Broadening EU cancer patients access to new theranostics solutions:  Proof of concept on securing EU onshore industrial and reliable supply of 211Astatine
4	Sampath	Kandala	Oncology Solutions General Manager	GE Healthcare	Enabling broader access to Theranostics solution in Europe
5	Aureli	Soria-Frisch	Director of Neuroscience BU	Starlab Barcelona	Neurotechnology as a Service (NTXaaS)

# IHI Call Days | Call 5

## Topic 2 - Theranostics



# Enabling broader access to Theranostics solution in Europe

Contact person name: Krisztian Horvath

Organisation: GE HealthCare

E-mail: [krisztian.horvath@ge.com](mailto:krisztian.horvath@ge.com)



GE HealthCare



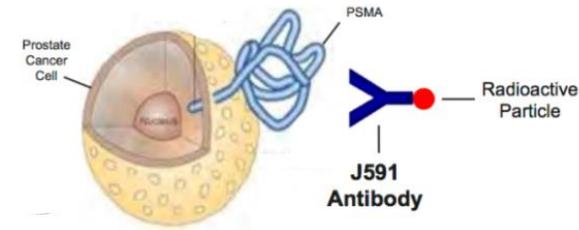
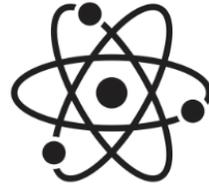
# 50 Challenges

- High and growing disease burden & prevalence of cancer (aging primary risk factor), ~1/4 of all deaths caused by cancer -> **200bn EUR cancer cost in EU**
- The clinical use of Theranostics therapies is limited to a few specialised centres in EU, while use-cases are being explored at increased speed -> **Patient access is suboptimal**
- Low clinical treatment capacities & expertise combined with supply chain and manufacturing vulnerabilities -> **Production & waste management inefficient, 3R issues**
- Limited arsenal of Theranostics guiding tools currently, new isotope development time-consuming process -> **increased time to market of new therapies**

## Objectives

- Reduce time to treatment for novel Theranostics pairs
- Enable more targeted therapies via better patient stratification
- Enable more efficient planning of clinical processes (incl. dosimetry)
- Develop a “Clinical Trial Master Protocol”
- Identify compound/nuclide combinations in cancer indications with high unmet medical need

# Main activities



- Evaluate Theranostics pairs for specific cancer indication (melanoma / breast / pancreas)
- Explore novel production processes minimizing radioactive waste
- Engage with national Member State regulatory hurdles & collaborate to create a streamlined market access & manufacturing environment
- Advance existing therapy guiding tools (e.g. dosimetry), explore potential AI - integration
- Develop and offer education and training materials as well as clinical guidelines on the use of theranostics solutions
- Develop a platform for clinical trial optimization, (different matched pharma kinetics profiles; explore how different ligands can be “switched”)



# Expertise and resources offered

- Engaged with 3 major clinical centers & industry partners (currently in discussion about WPs)
- External project management & subject matter expert available
- Extensive in-kind contribution available (infrastructure, manufacturing centres, AI expertise)

**Target budget of cca. 25m EUR**  
(50% in-kind, 50% EU contribution)

# Expertise requested

We are looking for external partners:

- Clinical & Academic partners with Theranostics infrastructure & expertise
- Pharma & biotech companies developing targeted Theranostic compounds
- Regulatory bodies



# Pitching Session

Today 27 June 2023, From 15:00 **Brussels time**

Join via the **B2Match platform**: <https://ihi-call-days.ihi.b2match.io/>

Number	First Name	Last Name	Job position	Organization	Title of the presentation
1	Ralf	Hoffmann	Principal Scientist	Philips	Prostate Cancer Theranostics
2	Ana	Blanco Sanchez	Grants and Innovation Coordinator	Quibim SL	Transforming imaging data into actionable predictions
3	Efrain	Araujo Perini	R&D Project Manager	Ion Beam Applications	Broadening EU cancer patients access to new theranostics solutions: Proof of concept on securing EU onshore industrial and reliable supply of 211Astatine
4	Krisztian	Horvath	Technical lead	GE Healthcare	Enabling broader access to Theranostics solution in Europe
5	Aureli	Soria-Frisch	Director of Neuroscience BU	Starlab Barcelona	Neurotechnology as a Service (NTXaaS)

# IHI Call Days | Call 5

- Topic 2: Development and proof of principle of new clinical applications of theranostics solutions

## Neurotechnology as a Service (NTXaaS)

Contact person name: **Aureli Soria-Frisch (PhD)**

Organisation: Starlab Barcelona

E-mail: [aureli.soria-frisch@starlab.es](mailto:aureli.soria-frisch@starlab.es)

Link to:

- Marketplace opportunity <https://ihi-call-days.ihi.b2match.io/marketplace/opportunities/UGFydGljaXBhdGlvbk9wcG9ydHVuaXR5OjUzNjYx>
- Participant profile <https://www.starlab.es/neuroscience>

**Starlab**<sup>®</sup>  
LIVING SCIENCE

# Brain Health needs a new approach

- Lack of modern decision tools for mental health and diseases
- Large misdiagnosis rates
- Large development costs on CNS drug development
- Difficult to find data on efficacy to support regulatory processes
- Lack of user-centric design in brain data services

## CNS HIGH RISK



**YOUR  
NEIGHBOR  
WITH  
EPILEPSY**

(50M PATIENTS  
WORLDWIDE)

**YOUR  
GRANDMA  
WITH  
ALZHEIMER'S**

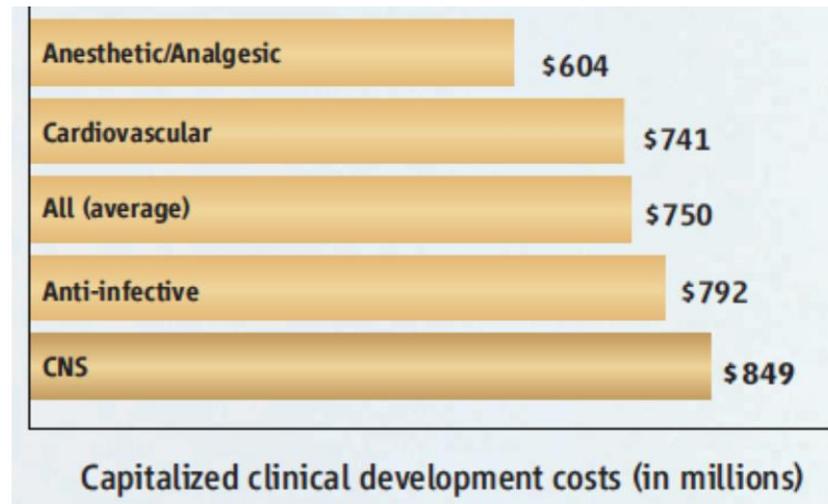
(90M PATIENTS  
WORLDWIDE)

**YOUR  
FRIEND  
WITH  
DEPRESSION**

(240M PATIENTS  
WORLDWIDE)

**YOUR  
DAD  
WITH  
PARKINSONS**

(5M PATIENTS  
WORLDWIDE)



20% PEOPLE  
MENTAL HEALTH  
PROBLEMS



# NTXaaS includes latest hardware



Dry electrodes



- Wireless dry EEG plus non-invasive stim (tCS)  
8, 20, 33 channels  
Medical Grade  
Hardware (CE, FDA)

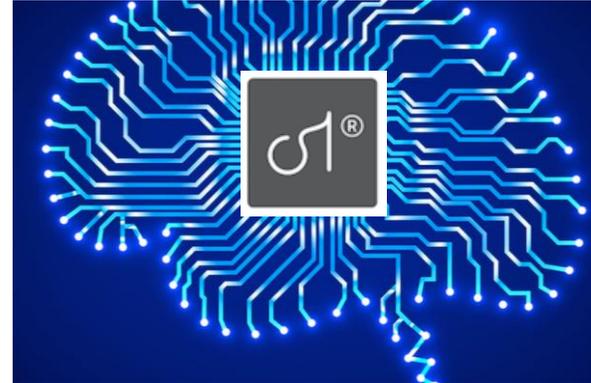
**Starlab**<sup>®</sup>  
LIVING SCIENCE

**iili** innovative  
health  
initiative

# Neurotechnology as a Service



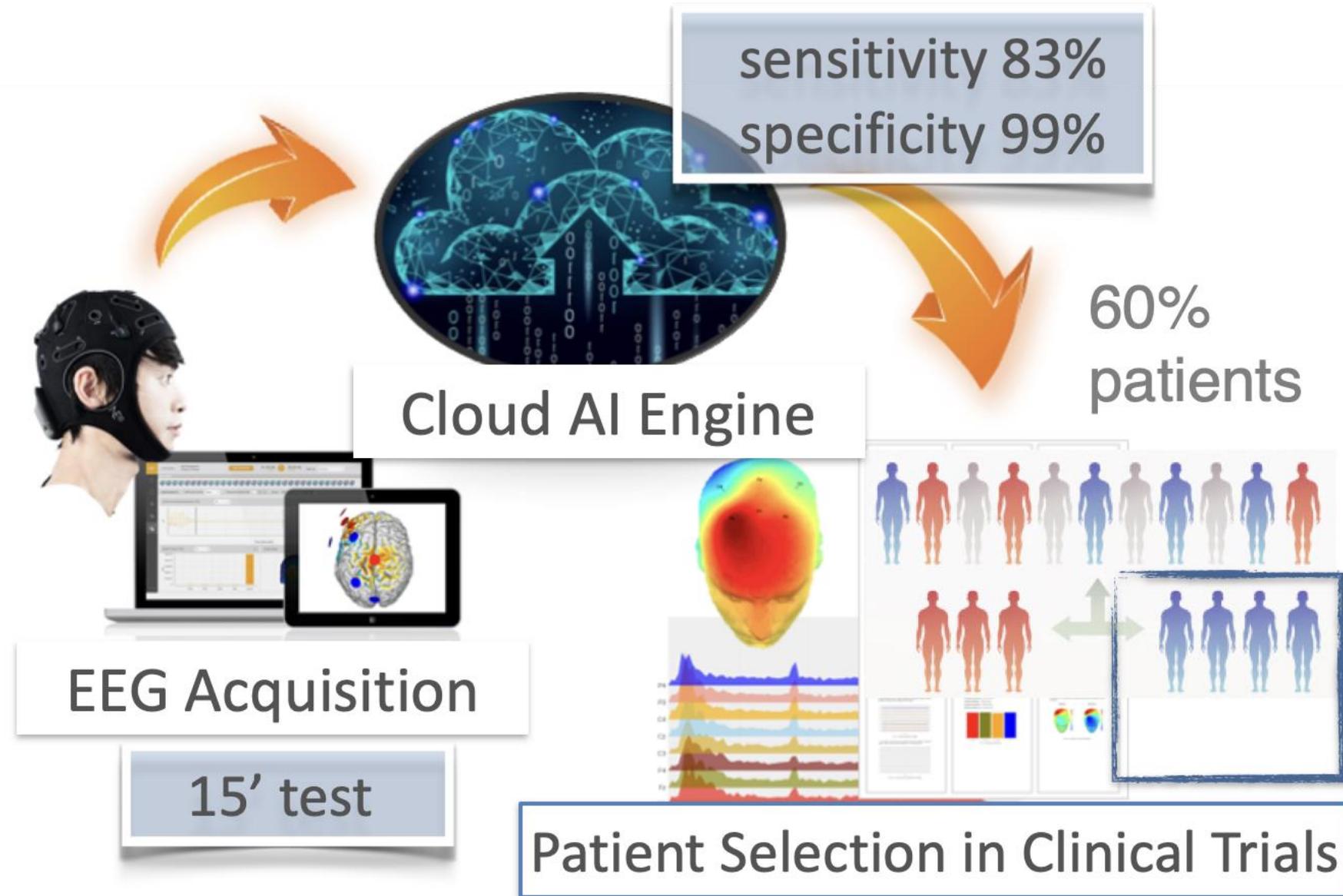
- Wireless dry EEG plus non-invasive stim (tCS)  
8, 20, 33 channels  
Medical Grade  
Hardware (CE, FDA)



- Machine learning platform for EEG, developed over 10 years
- Proprietary KAI framework

- Protocol preparation
- Data collection
- Advanced Signal Processing
- Machine learning for brain health, trial recruitment, and drug response

# NTXaaS for PD stratification



# Digital Biomarkers Portfolio

**Starlab**<sup>®</sup>  
LIVING SCIENCE



Looking for a  
building  
consortium

[info@starlab.es](mailto:info@starlab.es)

 innovative  
health  
initiative



Thank you for your attention

[ihi.europa.eu](http://ihi.europa.eu)

